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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,766	06/27/2003	David Wynn	MCP-5014 NP	7412

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
08/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,766	WYNN ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-23* is/are pending in the application.

4a) Of the above claim(s) *6,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-5,8-12 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/03/2007 has been entered.

Response to Amendment

Applicants amendments to the claims filed 07/03/2007 have been entered. Applicants have amended claims 1 and 19 and cancelled claim 7.

Response to Arguments

Applicant's arguments with respect to claims 1-5,8-12 and 15-23 have been considered but are not persuasive. The examiner is addressing applicant's arguments because the primary reference in the 103(a) rejection below Bucehler et al. is still employed.

Applicants assert that Bucehler does not disclose an immediate release compressed tablet dosage form.

The relevance of this assertion is unclear. Bucehler clearly discloses chewable products and discusses in detail chewable dosage forms such as tablets and the advantages of the composition disclosed in such applications. It is obvious that tablets

are compressed during normal manufacturing processes, therefore the new limitations are met by Bucehler in combination with the other references cited below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claim 21 lacks written description because while the claim and specification state that no more than a certain percent of water is left after drying at 105 °C the time in which the dosage form is dried was not recited. Therefore claim 21 lacks written description because the amount of water remaining after drying at high temperature would depend upon the time it was dried, therefore applicants have not described their limitation in the claims or specification in sufficient detail to practice their claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Specifically claim 20 recites that the dosage form meets USP dissolution requirements for immediate release, but the claim does not describe how the requirement would be met, ie time of dissolution, percent of active released and the conditions of the test. Therefore since claim 20 does not describe how a USP dissolution requirement can be met the claim is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5,8-12 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buehler et al. (US 6,432,442 B1, cited by applicant) in view of McTeigue et al (US 2002/0031552 A1) in view of Dressman et al (US 5,789,393, cited previouslycould com).

Buehler discloses a chewable pharmaceutical dosage form comprised by weight 1-20% gelatin, 10% hydrocolloid including HPC, up to 60% sweetener such as sorbitol and xylitol, the matrix further contains 2-30% of a taste masked coated pharmaceutically active agent including ibuprofen. See col 2 lin 40-56, col 3 lin 1-15, lin 43-col 4 lin 34 and claims. Incorporated by reference within Buehler is US 5,489,436 for its disclosed enteric coatings. 436' discloses the use taste masked coatings comprised by weight % of the total coating 5-95% cellulose acetate, an insoluble polymer and 5-95% dimethylaminoethyl methacrylate, a soluble polymer, the coating comprised 2-55% of the dry weight of the coated particle. See abstr col 4 lin 49-56 and col 6 lin 54-59 in US 5,489,436.

Buehler does not disclose the exact taste masked coating as claimed by applicants and Buehler is silent on the MW and viscosity in 2% aqueous solution of the HPC matrix.

McTeigue is used primarily for the disclosure within that taste masked pharmaceutical particles and chewable tablets made from those particles were well known in the art at the time of the invention. See abstract. The core of the taste masked particles could comprise numerous active ingredients including ibuprofen. See [0013] The taste masked coating preferably forms about 5-50 weight percent of the coated taste masked particles. See [0025]. The coatings disclosed within McTeigue comprised a) an enteric polymer such as HPMCP b) an insoluble film forming polymer such as cellulose acetate and c) surfactants such as polysorbates (polysorbate-80 was specifically disclosed in the examples). See [0015]-[0021] and examples. A particularly

preferred polymeric coating comprised about 53% wt HPMCP 43% CA and 4% polysorbate.

Dressman is used only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. See col 19 lin 65-col 20 lin 43.

Regarding claim 20 since by combination the compositions are the same their dissolution properties will also be the same, therefore the limitation on the USP dissolution profile is met be combination. Regarding claim 21 since by combination the compositions are the same their moisture content upon drying at the same temperature would obviously be the same.

Thus the claimed invention would have been *prima facie* obvious because the substitution of one known element such as the coating material disclosed within McTeigue for another known element such as the coating materials disclosed within Buehler would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The claimed limitations on the molecular weight of HPC would also have been obvious to one of ordinary skill in the art because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Thus since the use of HPC within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman applicants claimed HPC was a known option available at the time of the invention and someone of ordinary skill in the art would have a high expectation of

success in using the specific MW of HPC disclosed within Dressman and substitute those for the HPC disclosed within McTeigue.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER